UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,240	03/17/2004	Paolo Cavassini	BUG5-36500	5144

116 7590 01/15/2008

PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,240	CAVASSINI ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 10/23/2007 are acknowledged.

2. Claims 1-59 are included in the prosecution.

Response to Arguments

Rejection of claims 1-8, 22-40, and 46-56 under 35 USC § 103(a)

3. Applicant's arguments with respect to the rejection of claims 1-8, 22-40 and 46-56 under 35 USC § 103(a) as being unpatentable over Iijima et al. (US 4,948,589) have been fully considered. Applicant argues that Iijima does not teach the double layered coating and uses the hydrophobic agents like hydrogenated vegetable oil or carnauba wax as a binder and not as a layer. Applicant states that there is a difference in the process taught for forming the binder with respect to forming the over-coating layer. Applicant points out the more efficient delivery system and high concentration of choline chloride. This was found persuasive and rejections based on a new supporting reference, Riga et al. (US 6,174,890), follow.

Regarding applicant's statement that the double layered composition is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality (Applicant's Remarks, Page 3), the reference Iijima discloses that the granular composition is "capable of reaching an abomasums and downstream thereof substantially in the form of granules, without easily dissolved or decomposed in the rumen" (Iijima, Col. 2, lines 3-9). Furthermore, Iijima teaches that "when the coating is not applied, the desired resistance is not obtained" (Col. 9, lines 50-52).

Rejection of claims 9-14, 57-59 under 35 USC § 103(a)

4. Applicant's arguments with respect to the rejection of claims 9-14, 57-59 under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Richardson (US 6,797,291) have been fully considered. Applicant argues that the double layered particles of the claimed invention are advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality (Applicant's Remarks, Page 9). However, Richardson teaches compositions for stabilizing a hygroscopic bioactive substance, such as choline chloride and also providing adequate rumen protection in ruminant feeds (Abstract).

5. In order to cure the deficiency of the advantage of the carnauba wax as a second layer or overcoating layer, a new ground of rejection of Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291) follows.

Rejection of claims 15-19, and 41-42 under 35 USC § 103(a)

6. Applicant's arguments with respect to the rejection of claims 15-19, and 41-42, under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Brommelsiek et al. (US 5,766,668) have been fully considered. Applicant argues that the claims are rendered novel and non-obvious by the lack of teaching or suggestion, in both Iijima and Brommelsiek, that having the particles double-layered, as taught in the present application, is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality (Applicant's Remarks, Pages 9-10). In order to cure the deficiency of the advantage of the carnauba wax as a second layer or

overcoating layer, a new ground of rejection of Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Brommelsiek et al. (US 5,766,668) follows.

Rejection of claims 20-21 and 43-45 under 35 USC § 103(a)

7. Applicant's arguments with respect to the rejection of claims 20-21 and 43-45 under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Richardson (US 6,797,291), and further in view of Brommelsiek et al. (US 5,766,668) have been fully considered. Applicant argues that there is nothing in the three documents to suggest the advantages brought by the double layered particle as taught in the application, therefore the combination does not render the invention obvious. In order to cure the deficiency of the advantage of the carnauba wax as a second layer or overcoating layer, a new ground of rejection of Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291) and Brommelsiek et al. (US 5,766,668) follows.

Provisional rejection of claims 1, 9-11, 16-17, 50, 52-54, and 57 under obviousness type double patenting

8. In light of applicant's filing of a terminal disclaimer against copending Application No. 11/228,818, the provisional rejection of claims 1, 9-11, 16-17, 50, 52-54, and 57 on the ground of nonstatutory obviousness-type double patenting is withdrawn.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-8, 22-40, 46-56, are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890).

The claimed invention is a composition of matter comprising particles. Each particle comprises a core which contains choline chloride in the form of a dry, crystalline powder and a protective coating surrounding the core. The protective coating comprises an outer, continuous layer mainly consisting of carnauba wax, and an inner continuous layer consisting of a hydrophobic substance. Feed pellets, premix for feed, and mash feed containing the composition are also claimed.

Iijima teaches a granular composition containing choline for a ruminant. The granular composition is "capable of reaching an abomasums and downstream thereof substantially in the form of granules, without easily dissolved or decomposed in the rumen" (Col. 2, lines 3-9). Choline chloride is a preferable choline derivative (Col. 2, lines 45-46). Hydrophobic agents such as hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax are disclosed as binders and overcoating agents for the granules (Col. 3, lines 34-40 and lines 50-56). It is also disclosed that the granular composition may contain "any ingredients conventionally used in the animal feed, especially for a ruminant" (Col. 4, lines 9-15). The choline chloride is powdered since the particle size is disclosed. "Cholines having an average particle size of 100μm or less ... and a maximum particle size of 150μm or less ... are granulated with excipients and hydrophobic binders" (Col. 4, lines 18-27). The particle size of choline

chloride is achieved by grinding in an appropriate grinder (Col. 4, lines 42-46). Granulation methods such as fluidized granulation and agitation granulation are disclosed (Col. 5, lines 44-53). "... When the agitation granulation is used, relatively spherical or round granulated particles, which are suitable for subsequent coating, can be advantageously obtained ... the fluidizable binder is migrated to the surface of the granules during the granulation to form a surface layer. As a result, the cholines and other powder to be protected is relatively located in the inside portion of the granules" (Col. 5, lines 54-64). The resultant granules have a particle size of 0.5 to 2.5mm (Col. 6, lines 49-51). The choline granules "are overcoated with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, ... of a hydrophobic overcoating agent and a solubility modifier ..." (Col. 6, line 67 to Col. 7, line 6). "When the dissolution test of Example 1 was carried out with respect to the inner granules of Example 1 in which the overcoating was not applied, the dissolution rate in the rumen solution was 99%. As a result, the choline chloride was substantially completely dissolved in a rumen corresponding solution. Thus, when the coating is not applied, the desired resistance is not obtained" (Col. 9, lines 44-52).

Iijima does not expressly teach the overcoating of the choline chloride comprising an outer layer of carnauba wax and an inner layer of a hydrophobic substance.

Riga teaches a composition of enterosoluble units where a first layer of retardation is achieved by a polymer coating (of ethyl cellulose as the insoluble polymer) and "in the second step Carnauba wax is introduced in a ratio (wt/wt) of 1/0.47 -1/0.53

to the first retarder" (Col. 9, lines 15-22). The carnauba wax is used as a second retardant for the granule coating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, and specifically overcoating the first layer by an outer or second layer of retardant by using carnauba wax, as suggested by Riga, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Riga teaches prolonged release by using the carnauba wax as a second coating for the active containing granule (Col. 33, lines 38-50). Moreover, one skilled in the art would modify the components of the layers according to the desired stability of the core. Iijima teaches, "the binder and the overcoating agent may be the same or different, but the use of the same or similar substances is preferable because the good coating can be obtained when the compatibility of the binder with the overcoating agent is good" (Col. 7, lines 47-51). One skilled in the art would know the compatibility of hydrophobic components of the overcoating such as carnauba wax and hydrogenated oils. Moreover, one skilled in the art would know that carnauba wax melts at a higher temperature than hydrogenated vegetable oils and would use that as the outer layer or coating in order to further stabilize the coated granule in the rumen.

Regarding instant claim 1, the limitations of dry, crystalline choline chloride, coated with carnauba wax and a hydrophobic substance that is ruminally protected

would have been obvious to one skilled in the art over the teaching of Iijima (Col. 4, lines 18-27).

Regarding instant claims 2-4, the limitation of micronized choline chloride would have been obvious to one skilled in the art over the Iijima teaching of ground choline chloride and particle size of 150μm (Col. 4, lines 18-27). One skilled in the art would grind the choline chloride and vary the particle size in the composition in order to optimize the rumen protection.

Regarding instant claims 5-6, the limitation of choline chloride percentage in the core would have been obvious to one skilled in the art over the Iijima teaching of choline chloride coated core (Col. 6, line 67 to Col. 7, line 6). One skilled in the art would vary the amount of choline chloride in the core during routine experimentation, in order to optimize the efficacy of the coated composition. The recited percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 7-8, and 39-40, the limitations of the core comprising additional substance, particularly a flow modifier, would have been obvious to one skilled in the art over the teaching of Iijima where talc is used in the core composition along with choline chloride (Col. 8, Example 1 Granulation, lines 32-36). Talc is known as a flow modifier in the art.

Regarding instant claims 22-26, the percentages of the additional substances in the core would have been obvious to one skilled in the art over the teaching of Iijima

(Col. 8, Example 1 Granulation, lines 32-36). The percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 27-28, the percentages of the core weight with respect to the whole particle would have been obvious to one skilled in the art over the teaching of Iijima (Col. 8, Example 1 Granulation, lines 32-36). One skilled in the art would vary the percentage of core with respect to the coatings during the process of routine optimization.

Regarding instant claims 29-30, the percentages of the carnauba with respect to the outer layer would have been obvious to one skilled in the art over the teaching of Riga (Col. 9, lines 15-22). One skilled in the art would vary the percentage of carnauba wax with respect to the outer layer during the process of routine optimization.

Regarding instant claims 31-38, the limitations a rigidity-controlling agent mixed with carnauba wax would have been obvious to one skilled in the art over the teaching of Iijima. Iijima teaches hydrogenated palm oil, hydrogenated bean oil, hydrogenated coconut oil, stearic acid, carnauba wax etc. as hydrophobic binders (Col. 3, lines 34-40). One skilled in the art would find it obvious to combine the lower melting hydrogenated vegetable oils with the higher melting carnauba wax in order to control the rigidity of the coating layer. One skilled in the art would know that the rigidity of the outer coating layer is primarily provided by the higher melting carnauba wax, and by adding a lower melting point component (such as a hydrogenated vegetable oil) would modify the rigidity of the outer coating layer. The percentages of the rigidity-controlling agent would be obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 46-49, the limitations of outer coating percentage and inner coating percentage would have been obvious to one skilled in the art over the granule coating with carnauba wax taught by Riga (Col. 33, lines 47-49) and because the percentage of the inner and outer coatings would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

Regarding instant claims 50-54, the limitations of lipids as the hydrophobic substances would have been obvious to one skilled in the art given the teaching of hydrogenated oils and stearic acid by Iijima (Col. 3, lines 34-40 and lines 50-56).

Regarding instant claims 55-56, the percentage of the protective coating with respect to the whole particle would have been obvious to one skilled in the art over the overcoating "with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, ... of a hydrophobic overcoating agent and a solubility modifier ..." as taught by Iijima (Col. 6, line 67 to Col. 7, line 6) and because the percentage of the protective coating would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

11. Claims 9-14, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291).

The teachings of Iijima and Riga are stated above.

Iijima and Riga do not expressly teach silicates as flow modifiers.

Richardson teaches compositions for stabilizing a hygroscopic bioactive substance, such as choline chloride and also providing adequate rumen protection in ruminant feeds (Abstract). The choline chloride is encapsulated "with a lipid coating in an amount sufficient to retain at least about 60 wt % of the hygroscopic ingredient after the encapsulated ingredient is combined with the moist composition for a time period of at least about 1 day; and ... combining the encapsulated hygroscopic ingredient with the moist composition" (Col. 3, lines 41-47). The hygroscopic ingredient can be choline chloride (Col. 3, line 48). The moist composition is a ruminant feed (Col. 3, lines 54-55). Hydrogenated vegetable (soybean) oil is the preferred lipid for coating (Col. 3, lines 64-65). Hydrogenated vegetable oil can be mixed with lesser amounts of wax (Col. 3, line 66 to Col. 4, line 5). It is further disclosed that, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use silica as the flow agent, as taught by Richardson, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches, "skilled practitioners also recognize that flow agents, such as

finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

Regarding instant claims 9 and 10, the limitation of aluminosilicate would have been obvious to one skilled in the art over the sodium aluminosilicate teaching of Richardson (Col. 4, lines 6-11). Richardson teaches "the encapsulates can contain additives whose role is to facilitate the implementation of the techniques for preparing these encapsulates or to improve the physicochemical characteristics ... if included, these additives generally represent only a few percent by weight of the coating" (Col. 9, lines 46-62).

Regarding instant claim 11, the flow modifiers including silica would have been obvious to one skilled in the art over the silica teaching of Richardson (Col. 10, lines 11-13).

Regarding instant claims 12-14, the percentage of flow modifier would have been obvious to one skilled in the art over the Richardson teaching that "these additives are typically added in the range of 1 to 30 percent by weight" (Col. 9, lines 61-62).

Regarding instant claims 57-59, the limitations of the composition in feed pellet, premix for feed with the composition, and mash feed with the composition would have been obvious to one skilled in the art over the Richardson teaching that the encapsulated ingredient (choline chloride) is combined with a moist composition which is a ruminant feed (Col. 3, lines 54-55).

12. Claims 15-19, and 41-42, are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Brommelsiek et al. (US 5,766,668).

The teachings of Iijima and Riga are stated above.

Iijima and Riga do not expressly teach stearates as binders acting as moisture barriers in the core composition.

Brommelsiek teaches a choline feed stock precursor having greater than about 80-wt% of choline chloride, a lubricating agent, and an excipient (Abstract). Lubricants such as stearate salts are added to the spray drying system (Col. 7, lines 17-25). "The lubricant may be added during processing in concentrations which range from about 0 to 10 wt-% of the finished product ..." (Col. 7, lines 26-27). "The ratio of calcium stearate to choline chloride may range from about 0.01 to 1 to about 0.06 to 1" (Col. 7, lines 46-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Brommelsiek teaches that inclusion of stearate salts as lubricants is "useful in producing

a stable choline product ... this constituent assists in providing lubricity to the system during spray-drying and preventing deliquescence of the final composition" (Col. 4, lines 40-45). Since choline chloride is known in the art to be hygroscopic, using stearates to prevent the hygroscopic nature of the coated core of choline chloride would have been obvious to one skilled in the art. Even though Brommelsiek teaches spray drying liquid choline chloride, the end result is still a powdered choline chloride and lubricants are added to prevent deliquescence.

Regarding instant claims 15-19 and 41-42, the limitation of the binder and the percentage of binder acting as a moisture barrier in the core would have been obvious to one skilled in the art given the teaching of Brommelsiek that 0-10% of lubricant can be used in the composition (Col. 7, lines 26-27). One skilled in the art would vary the percentage during the process of routine experimentation.

13. Claims 20-21, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291) and Brommelsiek et al. (US 5,766,668).

The teachings of Iijima, Riga and Richardson are stated above.

Iijima, Riga and Richardson do not expressly teach silicates as flow modifiers or stearates as binders acting as moisture barriers in the core composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by

Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use silica as the flow agent, as taught by Richardson and lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches silica as a flow agent and Brommelsiek teaches lubricants such as stearates to reduce the hygroscopic nature of encapsulated choline chloride which has an impact on ruminant feed storage and stability.

Regarding instant claims 20-21, 43-45, the limitations of percent choline chloride in the core, percent of flow modifier silica, percent of calcium stearate, percent of protective coating (outer and inner layers), and final particle size would have been obvious to one skilled given the teachings of Iijima (Col. 6, line 67 to Col. 7, line 6), Riga (Col. 33, lines 38-50), Richardson (Col. 10, lines 11-13), and Brommelsiek (Col. 7, lines 26-27). One skilled in the art would vary the levels of the components and coatings in order to optimize the stability of the choline chloride in the rumen. The percentages and particle sizes recited are obvious variants unless there is evidence of criticality or unexpected results.

Conclusion

14. Due to the new grounds of rejection, this action is made non-final.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-

9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600